

NATIONAL ADVISORY COUNCIL FOR BIOMEDICAL IMAGING AND BIOENGINEERING (NACBIB) OPERATING PROCEDURES

I. STRUCTURE AND GENERAL OPERATING PROCEDURES

A. Council Membership and Structure

The Council shall consist of twelve members appointed by the Secretary, and eight non-voting ex officio members: the Secretary, Department of Health and Human Services, (DHHS); the Director, National Institutes of Health (NIH); the Director, National Institute of Biomedical Imaging and Bioengineering (NIBIB); the Chief Medical Director, Department of Veterans Affairs; the Assistant Secretary of Defense for Health Affairs; the Director, Centers for Disease Control and Prevention; the Director, National Science Foundation; and the Director, National Institute of Standards and Technology (or their designees). Of the twelve members appointed by the Secretary, six shall be from among scientists, engineers, physicians, and other health professionals who represent disciplines in biomedical imaging and bioengineering and six members shall be from among scientists, engineers, physicians, and other health professionals who represent other disciplines and are knowledgeable about the applications of biomedical imaging and bioengineering in medicine. Members are appointed for overlapping terms of four years, except that any member appointed to fill a vacancy for an uncompleted term shall be appointed for the remainder of that term. Members are not eligible for reappointment to the same Council or another NIH Council, until two years after the date of expiration of their term of office. Members may serve 180 days after the expiration of their terms until their successors have taken office. The chairperson of the Council shall be the Director, NIBIB.

B. Council Role and Function

The Council provides the second level review of research and resource grant applications assigned to NIBIB, focusing primarily on the relevance to the programmatic missions and priorities of the Institute, as well as funding and other policy considerations. The Council also reviews the adequacy of the scientific review by initial review groups, and makes recommendations to the Director, NIBIB, and the Director, NIH, on these considerations.

The Council shall review the program activities of the NIBIB, and provide advice and recommendations concerning these activities to the Director, NIBIB. The purpose of this review is to:

- C ensure appropriate use of grant, cooperative agreement, and contract funds in the Institute's support and conduct of research and related activities;

- C ensure that NIBIB is responsive to public needs;
- C assist the NIBIB in establishing objectives and priorities, allocating resources, and enhancing program management and effectiveness.

C. Council Meetings

The Director, NIBIB will select the time and location of the meetings. As required by the Government in the Sunshine Act (P.L. 94-409), notices of Council meetings will be published in the Federal Register. These meetings will be divided into open and closed sessions. During the public open session, the Director, NIBIB will report to Council members on major program and policy issues, as well as information about legislative and budget issues, and adequate time will be reserved for discussion of these items. Additional information items will also be presented during this portion. Only those segments of the meetings focused on review of grant applications may be closed to the public.

A quorum of the Council consists of a majority of the appointed membership of the Council; ex officio members shall not be included in establishing a quorum. When a vote of the Council is required, a simple majority of appointed members provides concurrence.

D. NIBIB Support for Council Activities

Liaison—The Director, Division of Extramural Activities is designated the Executive Secretary of the NACBIB, and is responsible for liaison between the Council and the NIBIB staff, and for follow-up of Council recommendations.

Assistance to the Council--The Director, NIBIB, will make necessary staff and funds available to enable the Council to discharge its statutory responsibilities.

E. Confidentiality of Review Materials

To ensure the confidentiality of all material relating to the review of grant applications (i.e., applications, scientific review group summary statements, staff recommendations, and other similar documents), Council members will leave all such material in the conference room following the completion of the meetings.

Any confidential materials mailed to Council members may be burned, shredded, or returned to NIBIB. Written notification of such disposal shall be sent to the Executive Secretary of the Council.

Under no circumstances should a Council member discuss any actions relating to the review of specific grant applications with applicants. The Executive Secretary of the Council is to be alerted if an applicant contacts a Council member with respect to an application. The following language is suggested for use by Council members in

response to queries from applicants regarding the review of applications prior to Council review. “This will acknowledge receipt of your letter of [date], concerning the review of your application [insert activity code and application number]. In accordance with the procedures followed by members of the National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB), I am forwarding your letter to the Executive Secretary, NACBIB, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health. I am confident the Executive Secretary will ensure proper review of your application within the established policies of the NIH review system.”

F. Conflict of Interest

Council members may not participate in activities that violate conflict of interest laws and regulations. Council members should not participate in, nor be present during the review of any grant application or project in which, to the member's knowledge, he/she, his/her spouse, parent, child, or close professional associate: (1) has a financial interest; (2) is serving as an officer, director, trustee, partner, or employee, or is otherwise similarly associated; or (3) is negotiating or has any arrangement concerning prospective employment or other similar association.

G. Conflict of Interest Procedure

To avoid conflicts of interest, a Council member shall leave the conference room when an application or proposal submitted by an organization fitting the criteria described above in paragraph F is being discussed. The DHHS Office of Government Ethics has provided a regulatory waiver which provides that faculty of state multi-campus institutions of higher education who serve as experts and consultants to the DHHS may participate in matters affecting one campus, if the employee's disqualifying financial interest is employment at a separate campus of the same multi-campus institution. NIH policy, accordingly, permits peer review advisors from those institutions to recommend on matters involving campuses other than those where they have professional responsibilities. Under this waiver, a member from the University of California at Los Angeles, for example, will not be required to leave the room when an application from the University of California at Berkeley is being discussed, unless there is some reason other than simple employment as to why a conflict of interest might exist.

In addition, a committee member who is employed by a private institution and/or one of its affiliates may participate in the review of a grant application submitted by an affiliate of the private institution, if the member does not hold a joint appointment with that affiliate, the member does not have affiliate-wide responsibilities, and the member has a waiver to do so.

At the beginning of each Council meeting, the Executive Secretary will remind Council members of policies regarding conflict of interest. At the time of the meeting, each Council member will also sign the following conflict of interest statement:

This certifies that in the review of applications conducted by the National Advisory Council for Biomedical Imaging and Bioengineering on [date], I absented myself and did not participate in the discussion of, nor vote on, any application in which to my knowledge, I or my spouse, parent, child, or close professional associate has a financial interest nor on any application from an organization, institution, or university system where to my knowledge, I or my spouse, parent, child, or close professional associate is an employee, consultant, officer, director, partner, or trustee, is negotiating for employment, or otherwise has a financial interest.

In Council actions in which we voted on a block of applications without discussing any individual application--the en bloc actions--my vote did not apply to any application from any institution fulfilling the criteria in the preceding paragraph.

H. Operating Procedures Review

Once each year, during the open session of a meeting, the Council will have the opportunity to review and update these Operating Procedures. This review will be scheduled generally for the January/February meeting of Council.

I. Subcommittee Procedures

The Council may establish ad hoc or standing subcommittees. The quorum for a subcommittee will be three. Subcommittee members will be appointed by the Director NIBIB. Like full Council meetings, subcommittee meetings will be open to the public. Subcommittees shall report to the full Council.

II. Procedures for Review of Grant Applications

A. General Review Procedures

All voting members will have electronic access to all available summary statements to be reviewed at the NACBIB meeting prior to the meeting. Applications with primary and dual institute assignment (i.e., with primary assignment to another Institute) will be routinely available to members for review. At any time prior to the Council meeting or during the meeting, members may request a copy of any application and summary statement under review.

Applications Not Recommended for Further Consideration (NRFC) will not routinely be reviewed by the Council. Unsourced applications will not be presented for consideration by Council.

B. Council Discussion items

During application review, Council will give individual consideration to some types of applications. Applications within these categories will be assigned to two Council members for presentation, with the exception of Council Initiated Items that will be brought forward by the selecting member(s).

Council Initiated Items: Council members may select any application under review for Council discussion. For each selected application, the Council member should send a brief written description of issues to be discussed to the Executive Secretary, NACBIB for distribution to other Council members, not later than seven days prior to the Council meeting.

Appeals: Correspondence from applicants communicating their concerns to NIBIB staff about the review of their applications will be provided to Council. NIBIB will bring to Council any appeals submitted during the time between the meeting of the Initial Review Group and the administrative cut-off of seven days before Council. Appeals submitted after this cut-off will be considered at the following Council meeting or through an interim process. The Council has two options: (1) recommend re-review by the same or a different SRG; or (2) concur with the initial review.

MERIT nominations/extensions: Council will review all recommendations for MERIT awards/extensions. NIBIB staff or Council members may recommend applicants for MERIT consideration. MERIT nominations will be reviewed annually at the May Council.

Initiatives: Staff recommendations for support of applications received in response to NIBIB Requests for Applications generally will be brought before Council. When staff anticipates an unusually large volume of applications in response to Requests for Applications, the staff may request that Council allow early en bloc concurrence for applications included within the program plan for these initiatives.

Applications received in response to program announcements (PA), program announcements with set-asides (PAS), or specific receipt dates (PAR) will be included with en bloc lists.

Foreign grant applications: Council will review all applications from foreign institutions recommended for funding by NIBIB staff.

Human Subjects Concerns, Animal Concerns, Gender Concerns, Minority Inclusion Concerns, Children Concerns: Any application coded for violations of NIH policies regarding: human subjects; protection of animals; or inclusion or women, minorities or children will be brought before Council for review.

Once each year, the staff will set aside time during the Council meeting to discuss the protection of human subjects and animals in research. As part of this discussion, the staff will provide Council with a report on the Institute's compliance with these

policies.

Special Considerations: Applications outside the program plan, recommended by staff for support fall in the category of Special Considerations. Council will consider these applications individually.

C. En Bloc Actions

Applications not requiring individual discussion will be treated en bloc at the Council meeting. The en bloc list will include all applications with scores within the program plan that may potentially be funded by the NIBIB. Unless requested by Council, these applications will be reviewed en bloc. The Director, NIBIB may not fund any application, unless it has been recommended for consideration for funding by an SRG and the NACBIB.

D. Early En Bloc Concurrence

In an effort to streamline en bloc concurrence with Scientific Review Group recommendations and to expedite funding actions, the NACBIB will use early en bloc concurrence. Only applications with scores well within the program plan will be reviewed using the early en bloc concurrence process. Early en bloc concurrence will not be used for any applications within the following categories:

- C human subject, animal, or biohazard concerns;
- C foreign institutions;
- C issues regarding recruitment of women, children and minorities or data monitoring;
- C identified by a Council member to be of special concern;
- C any special policy issues;
- C previously deferred by Council for additional information or for re-review; or
- C identified by NIBIB staff as requiring special consideration (e.g., high program priority, applications with high costs, restoration of time, etc.) or discussion by Council, with the exception of the occasional review of applications received in response to RFAs. Use of early en bloc concurrence for these NIBIB initiatives must be pre-approved by Council.

The procedures to be followed are:

1. The Chairperson of the NACBIB will select 3 members of Council to provide the en bloc concurrence on behalf of the full Council. Members selected for this function may change for each Council cycle.
2. The Executive Secretary of the NACBIB will determine which applications are eligible for the early en bloc process.
3. The selected Council members will be provided with all review materials,

including summary statements through the Electronic Council Book.

4. The remaining Council members will also have access to the list of applications in the en bloc concurrence, as well as the summary statements, through the Electronic Council Book.
5. Council members, including ex officio members, may determine that an application should come to the full Council for discussion or should not be expedited for any reason. Members must notify the Executive Secretary of the results of their review, including any requests to remove the application from the en bloc list within ten (10) days of the availability of early en bloc concurrence applications.
6. A report of the early en bloc recommendations will be presented at each Council meeting.

Applications with no special considerations or concerns will be eligible for funding as soon as the Council reviewers have certified to the Executive Secretary of Council that the review is complete.

E. Council Review Recommendations

The following options are available to Council for all applications under review:

- Concurrence with all recommendations of SRG
- Concurrence with SRG scientific/technical assessment with alternate recommendations for non-scientific portions of application.
- Non-concurrence with scientific/technical assessment and deferral of the application for review by same SRG again or a different study section.
- Non-concurrence with scientific/technical assessment and a recommendation for no further action. These applications cannot be considered for funding by staff.

III. Staff and Interim Administrative Actions

The staff may take the actions described below without Council review. Council may request information on these actions at any time. At each regular NACBIB meeting, NIBIB staff will provide to Council a listing of all administrative actions completed since the last regular meeting, with the exception of items A and C below.

A. Transfer of Research Grant for Investigator Who Moves to a New Institution

NIBIB staff may make research grant awards equal to the anticipated committed support for continuing work under the same principal investigator when he or she moves from

one institution to another. Approval will not be automatic; NIBIB staff may consult with the appropriate study section or Council as necessary.

B. Approval of New Principal Investigator or Program Director

NIBIB may approve a new or interim principal investigator or program director to continue an active grant.

C. Extension of Project Period Dates

NIBIB may extend project period dates without additional funds.

D. Authority to Restore Budget/Years

NIBIB staff may make awards that appropriately restore funds up to \$100,000 direct costs or one year deleted by an initial review group.

E. Scientific Review and Evaluation Awards

NIBIB staff may take final action in awarding supplements to the chairpersons of the NIBIB research and training review committees in an amount necessary to carry out the functions of the committees.

F. Awards for Orderly Termination or Interim Support

NIBIB staff may make appropriate awards for orderly termination or interim support of competing continuation applications that were either not recommended for further consideration (NRFC) or recommended with a priority too poor for payment; this procedure is to be used in those cases where sudden termination of the grant would cause a serious loss of scientific material or impose a hardship to already employed personnel. In such cases, (1) the award usually should be for a period of less than twelve months, (2) careful review should be given to the need for salaries and consumable supplies, (3) usually no funds should be provided for additional equipment or travel, and (4) in the case of training grants, stipend support should be provided for completion of training for those trainees already appointed.

G. Awards for Interim Period Due to a Deferral

NIBIB staff may make an award for an appropriate amount and period of time when a recommendation of deferral on a competing continuation application results in a loss of continuity of the active research or training program.

H. Authority to Increase Grant Award Ceilings

NIBIB staff may make supplemental awards or adjustments when additional funds are necessary above the amount previously recommended to carry out the scientific, administrative and fiscal intent of the grant as previously awarded, with the following limitations.

- Council approval is not required for supplements under the NIH programs to promote reentry into biomedical and behavioral research careers and to increase involvement in biomedical research of underrepresented minorities and individuals with disabilities.

- Supplements up to \$100,000 direct costs per year may be made to research grants, career awards, cooperative agreements, and training grants.
- Supplements up to \$200,000 may be made to research center grants or program project grants.

I. Authority to Increase Training Slots

NIBIB staff may increase the number of permanent slots supported on T32 grants by up to two slots without Council approval.